

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1615

PATEL ET AL.

APPLICATION NO: 10/743,366

FILED: DECEMBER 22, 2003

FOR: MODAFINIL COMPOSITIONS

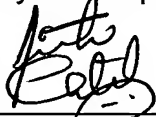
**DECLARATION UNDER 37 C.F.R. §1.131**

We, Ashish Anilbhai Patel and Gary Barbera, make the following declaration in connection with the above-identified patent application.

1. We are co-inventors of the invention claimed in the above-identified patent application.
2. I, Ashish Anilbhai Patel, am a citizen of India, residing at 18 Petunia Dr., Apt. 1H North Brunswick, NJ 08902. From 1999 to 2005, I have been employed by Sandoz in the Research and Development Department located in Dayton, NJ, as a Research Scientist.
3. I, Gary Barbera, am a citizen of the United States, residing at 17 Huntington Circle Dr. Medford, NJ 08055. From 2001 to 2005, I was employed by Sandoz in the Research and Development Department located in Dayton, NJ, as a Research Scientist. I left Sandoz in 2005 to join the Research and Development Department of Par Pharmaceutical, located in Woodcliff Lake, NJ, as a Research Scientist, where I am currently employed.
4. We have read page 2, lines 10 to 11, of the Office Action from the U.S. Patent and Trademark Office, dated March 21, 2005.
5. We conceived and reduced to practice the invention claimed in the above-identified patent application in the Research and Development Department of

Sandoz located in Dayton, NJ, prior to November 24, 2003, which is the U.S. filing date and 35 U.S.C. 102(e) date of U.S. Patent Application Publication No. 2004/0105891 (Bentolila), as evidenced by the laboratory notebook pages 822-5-185 and 822-5-160(a), a copy of which are attached hereto as Exhibits 1 and 2, respectively, with the dates blacked out. Applicants laboratory notebook page 822-5-185 shows a pharmaceutical composition containing modafinil and calcium silicate, and references laboratory notebook page 822-5-160(a) as the lot number for the modafinil used in the composition. Laboratory notebook page 822-5-160(a) sets forth a sieve analysis worksheet for the modafinil used to prepare the modafinil composition. According to page 822-5-160(a), 21.62% of the cumulative total of modafinil particles have a particle size greater than 212 microns, which is within applicants claimed range of 5 to 50%. Thus, applicants conceived and reduced to practice one embodiment of the invention as claimed in the above-identified patent application prior to November 24, 2003, which is the U.S. filing date and 35 U.S.C. 102(e) date of U.S. Patent Application Publication No. 2004/0105891.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Ashish Anfibhai Patel

Date: 8/4/05



Gary Barbera

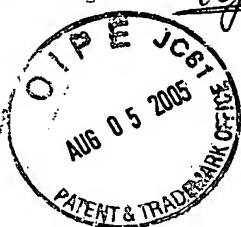
Date: 8/1/2005

TITLE Modafinil 200mg.

Book No. \_\_\_\_\_

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to make Modafinil blend by replacing Mg Trisilicate  
 & Micro-cel (C) (Synthetic Calcium Silicate) on  
 mg basis in 822-5-134. Rest of the formula  
 remains same.

Formula:-

Items #	R.M.#	Lot #	Ingredients	mg/unit	g/15 tabs (gm)
1	R646	822-5-160(a)	Modafinil *	200.0	5.00
2	-	DS02-L-563	Micro-cel - C	25.0	0.625
3	R115	D107400	Lactose FF	217.5	5.4375
4	R112	D105294	Starch 1500	25.0	0.625
5	R142	D912048	Ac-di-ssl.	25.0	0.625
6	R116	D009469	Mg-stearate	7.5	0.1875
				<u>500 mg.</u>	<u>12.5 g.</u>

\* Milled through 0.075" screen.

Procedure:- Same as 822-5-134.

Composition:-

Press:- 0.7 ton

Thickness:- 0.217"-0.219"

Hardness:- 10 cc

} 6 tabs submitted for dissolution.

Comments:-

- ① Flow of final mix looks better compared to Mg-trisilicate.
- ② Tablet surface was good & better hardness. Can hear clear snap upon breaking.
- ③ Tablet ejection from die was better than Mg-trisilicate.
- ④ Tabs <sup>which</sup> dropped in dissolution

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To Page No. \_\_\_\_\_

Witnessed & Understood by me, \_\_\_\_\_

Date \_\_\_\_\_

Invented by \_\_\_\_\_

Date \_\_\_\_\_

Recorded by [Signature]

# Exhibit 2

## Sieve Analysis Worksheet

Drug Substance or

Product: Modafinil API

Aerosil used (Y/N): Yes

822-5-160 (A)

milled 0.079"

Lot#:

screen

% of Aerosil:

1 % w/w

Operator: G.Barbera

Date:

ATM Sonic Sifter

GPTC 11154

Instrument ID: QCE# 88

Balance ID: QCE# 138

Notebook # & page: DLT-166-40

sample weight (g): 4.2812

Sieve#/Part	Size (um)	Tare (g)	Gross (g)	Retained (g)	% retained	cumulative % retained
60	250	38.2307	38.9890	0.7583	17.97	17.97
70	212	36.3071	36.4615	0.1544	3.66	21.62
170	90	33.5247	34.0182	0.4935	11.69	33.32
230	63	33.5607	33.9637	0.4030	9.55	42.86
325	45	31.0817	31.5313	0.4496	10.65	53.51
400	38	30.0844	30.4779	0.3935	9.32	62.84
bottom	thru 38	21.0827	22.6513	1.5686	37.16	100.00

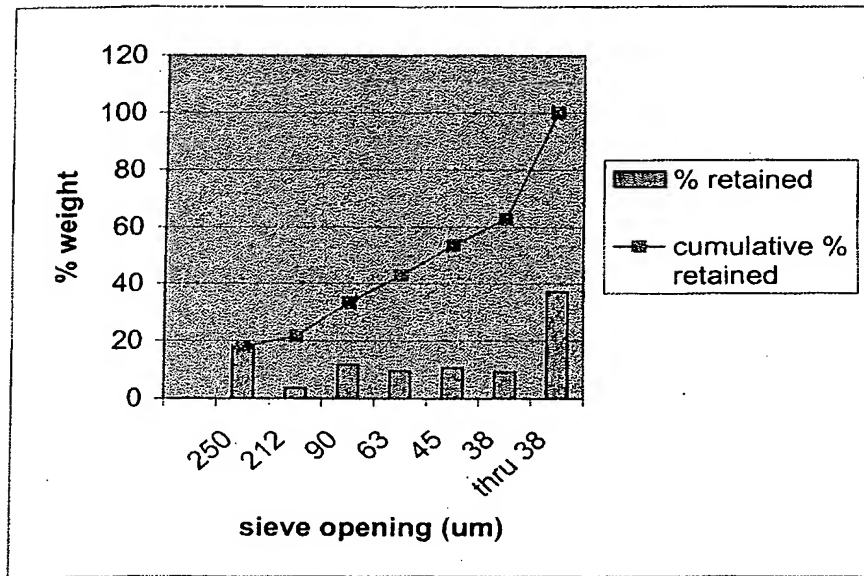
total (g): 4.2209

start sample

(g): 4.2812

difference (g): 0.1

% difference: 1.4



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